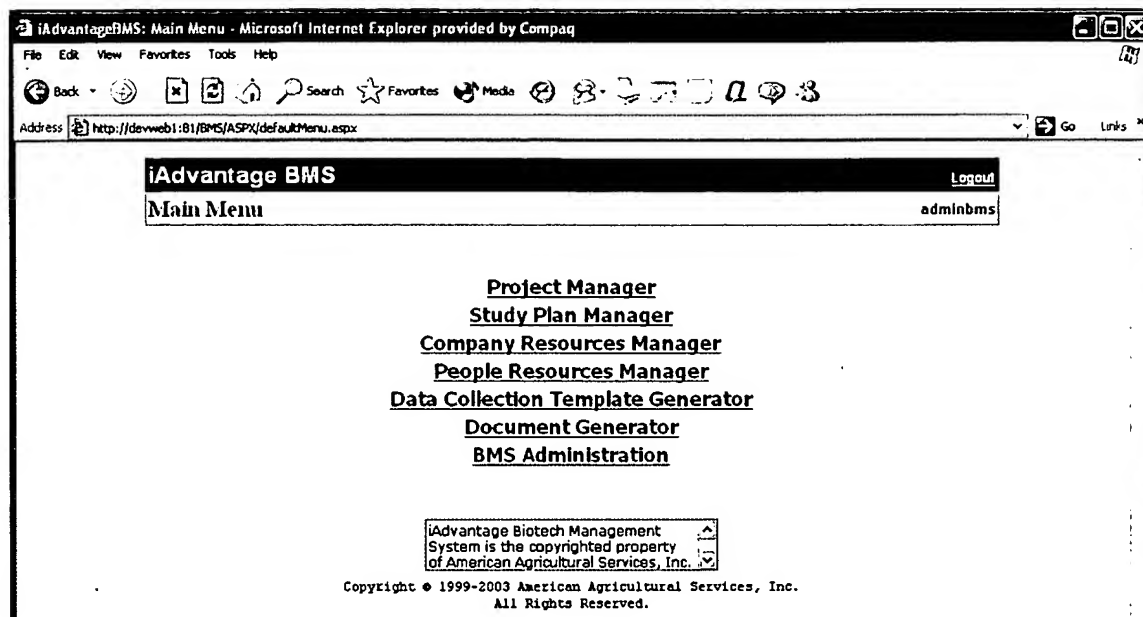
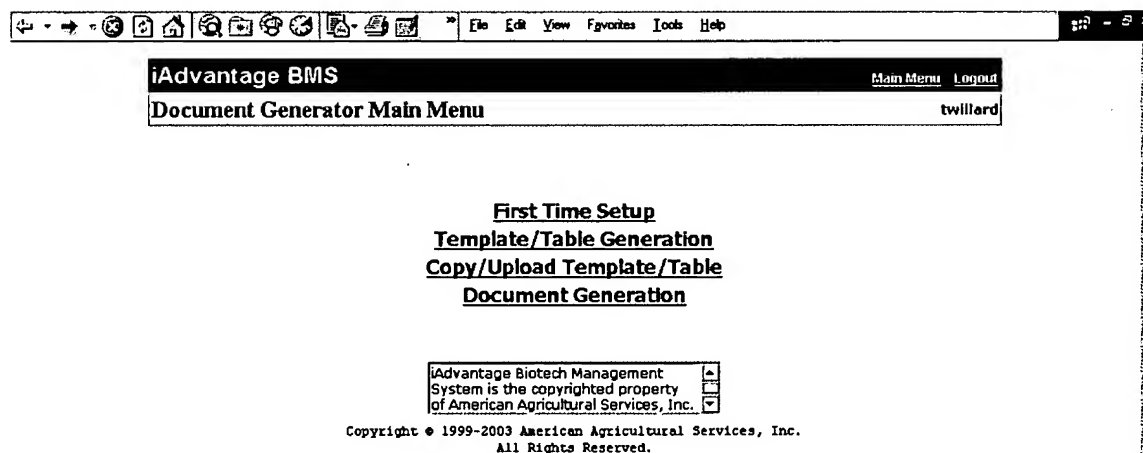


8. Document Generator - Main Menu



5 Select Document Generator from the BMS Main Menu



10 This menu allows the user to choose what phase of document generation they want to enter. In “Document Generator” the user can create report templates, tables and final reports.

First Time Setup – Allows the user’s computer to be setup so that the DocGen variable list and functions work correctly.

15

Template/Table Generation – Allows user to create various tables and templates that may be used to create documents from the data in the database. Use of templates allows users to create the same or similar documents for different studies or across studies.

Copy/Upload Template/Table – Allows user to upload the templates and/or tables created to the host system for access by user or other eligible users.

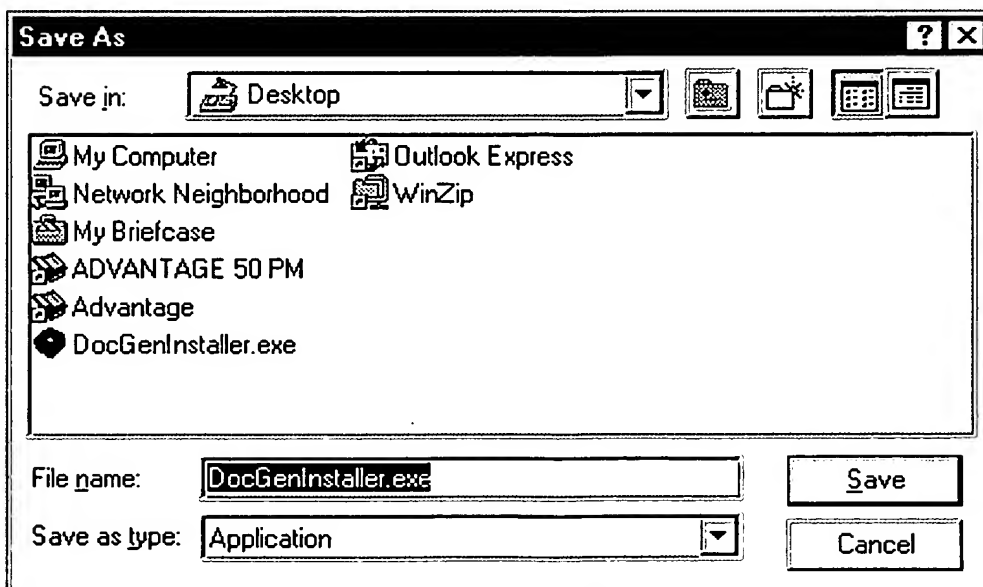
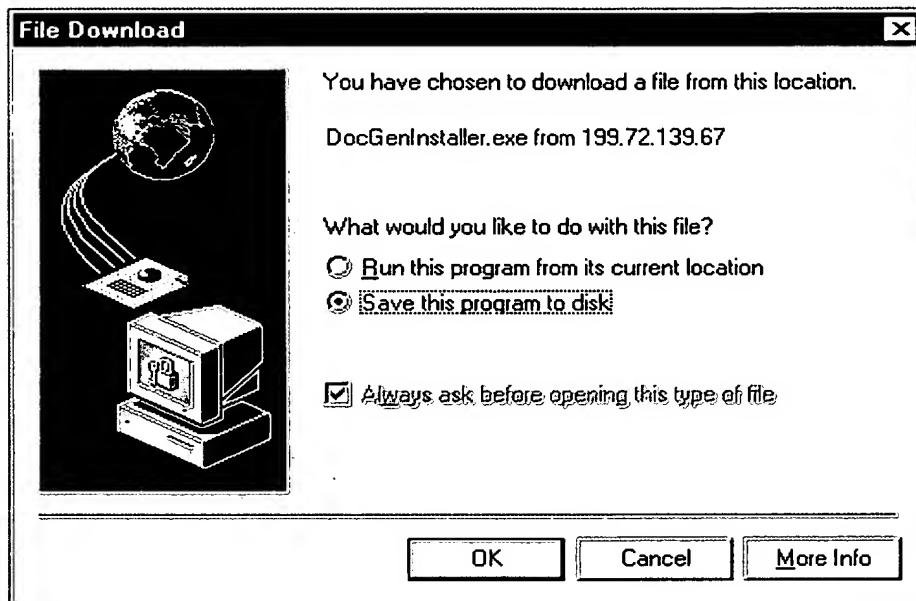
- 5 **Document Generation** – The Final Phase of document generation in which the user may use the templates and tables created to produce final documents for single or multiple parameters.

In the upper right-hand corner is the Log-out link and the Main Menu link.

8.2 Document Generator – First Time Setup

After clicking on the “First Time Setup” selection the screens similar to those in the following section will appear which will let the user determine the location of the files to be saved to the user’s computer. These files are necessary to be able to use of the Document Generator. This function will need to be run the first time the user enters the Document Generator section of the software. Once it is loaded on that computer it will not have to be loaded on that computer again.

10 Example screens of download process.

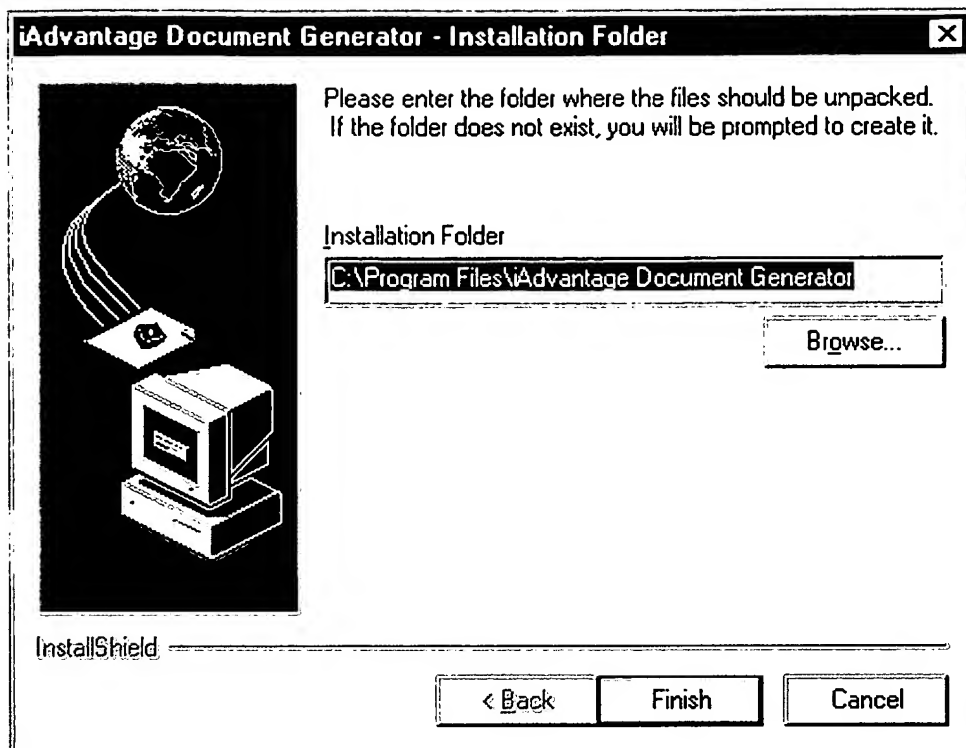


15

- After the DocGenInstaller.exe file is downloaded to the location on the user's computer that was specified by the user, the program will need to be run to allow it to setup the users computer to be able to run the Document Generator. User will minimize the web browser screen, locate the DocGenInstaller.exe file on their computer and then double click on the file to start the application. The "iAdvantage Document Generator – Installation Folder" box will appear.
- 5

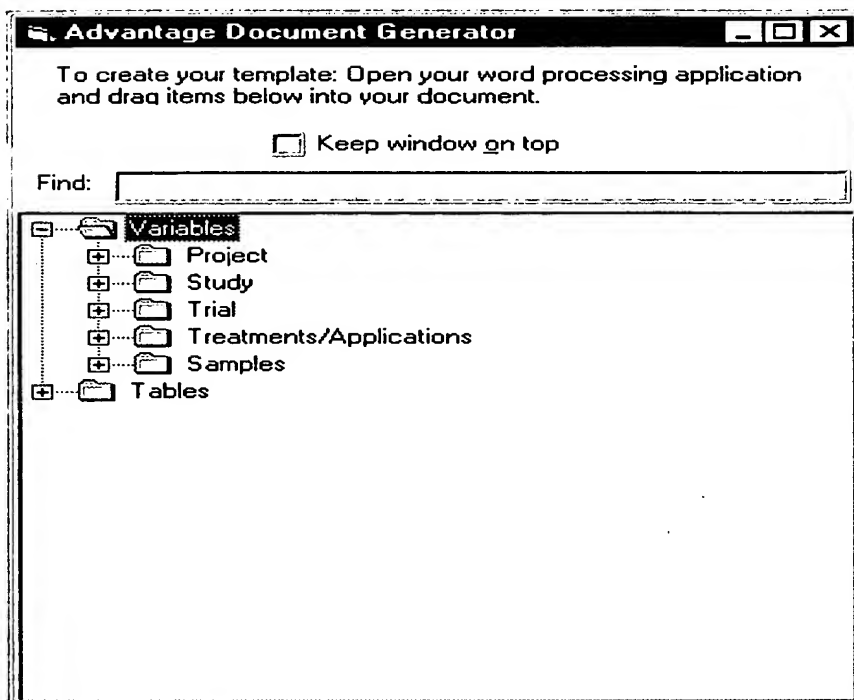


- 10 The following screen or screen similar to this will appear which will allow the user to complete the installation process for the Document Generator files that need to be located on the user's computer.



8.3 Document Generator – Template/Table Generation

- 5 This will be the first screen the users will see when they select “Template/Table Generation” from the Document Generator Main Menu. This section of the program allows the user to create tables and report templates utilizing the information and data from the iAdvantage BMS database. To create report templates this screen will be used in conjunction with a word processing software to create the templates which can contain text, tables, and variables. Tables are created solely in iAdvantage without the need of a word processor.



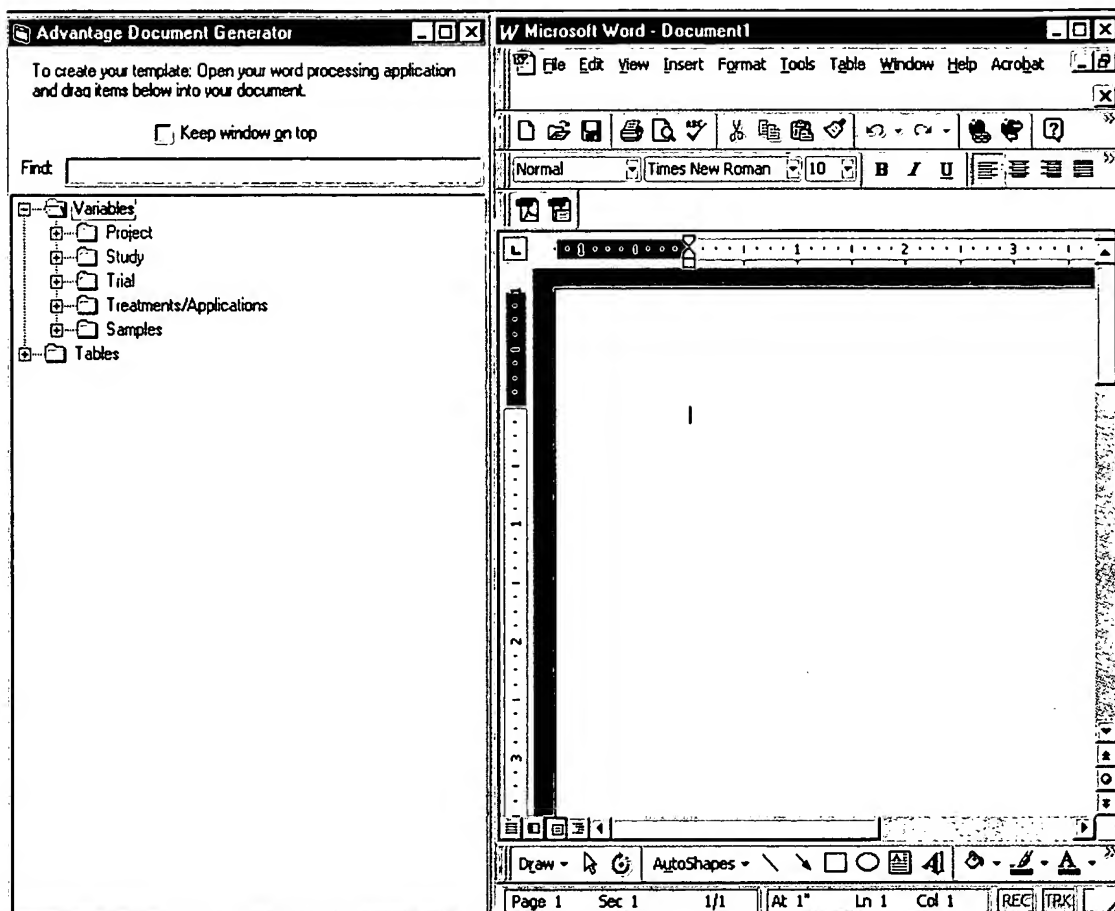
- 10 **Keep window on top** (checkbox) – Clicking on this box will place a check mark in the box and will keep this particular box as the top screen viewed even though other software and/or screens may be open at the same time. Even if working in another screen this box will always remain on top.

- 15 **Find** (entry field, alphanumeric, unlimited)– The user can type in the name of a variable they wish to find into this field and it will be shown in the Variables or Tables tree in the box below this field. As the user types, the program will search for variable names that match what is being typed in the Find field as it is being typed. The first variable matching what has been typed so far will be displayed in the tree. That variable may then
- 20 be selected from the tree, by clicking on it.

- 25 *The Find feature should be used carefully. There are many variables with the same display that occur in many different variable folders. Selecting the variable from the wrong variable folder can result in errors in the output of document generator.*

- Variables & Tables Box** – The folders in this box may be clicked on to reveal the subfolders or variables/tables beneath it. The “+” or “-” symbols beside each folder also allow opening and closing of the folders in the tree. The “+” symbol may be clicked on to reveal the subfolders or variables/tables beneath it and the “-” symbol clicked on to close the tree to only show the folder name beside it.

Variable & Tables Box - Drop & Drag Feature

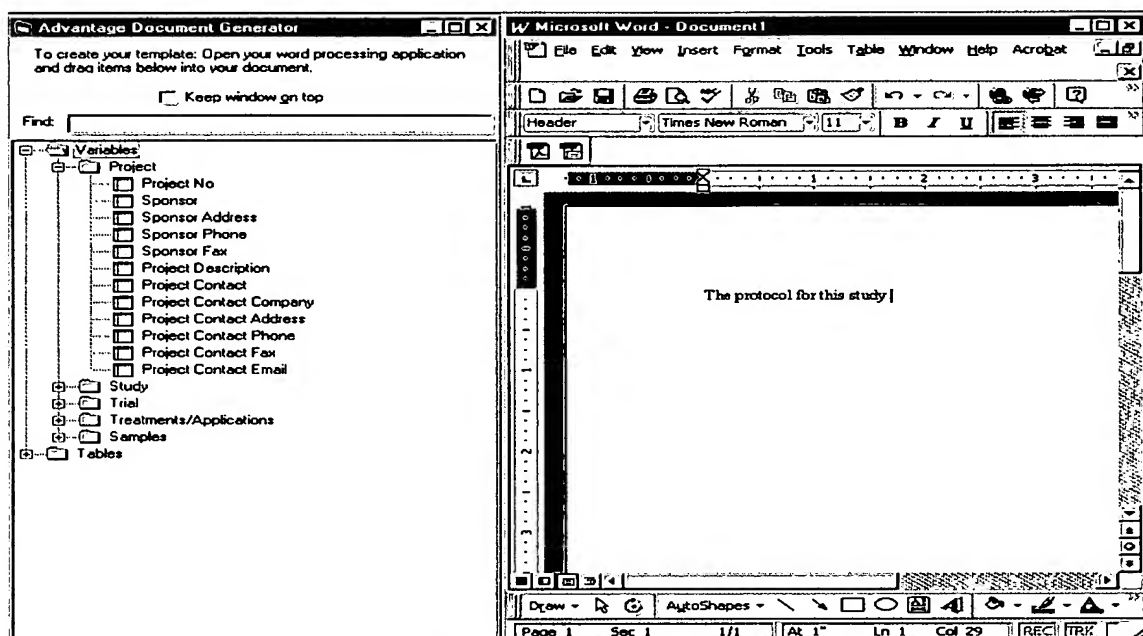


- To create report templates the Variables and Tables box must be used in conjunction with a word processing software such as Word or WordPerfect. To do this the User will open a document in the Word Processor and then reduce the screen size so that it and the Variables and Tables Box fit on the screen side by side. **This will allow the variables and tables to be copied (drag & drop) into the word processor document.**
- 15 Selecting Variable or Table** – Variables and Tables will be selected from the tree in the Variables and Tables Box by clicking and holding down the left mouse button while the cursor is sitting on top of the variable or table that the user wants to move into the template.

Placing Variable/Table in Template – While still holding down the left mouse button the user will move the cursor over to the appropriate location in word processor document and release the mouse button. The variable/table title will now appear in the word processor document in that location.

When a Variable is dragged and dropped into the template document the variable name will appear with double asterisks (**) before and after the variable name. When a table is dragged and dropped into the template document the table name will appear with double asterisks and the letter TBL (**TBL) before the table name and double asterisks (**) after the table name.

Text may be entered into the document before, during or after the placement of the variables and tables in the document. This process may be repeated until all the desired variables and tables have been placed in the document. This will continue until template is completed.



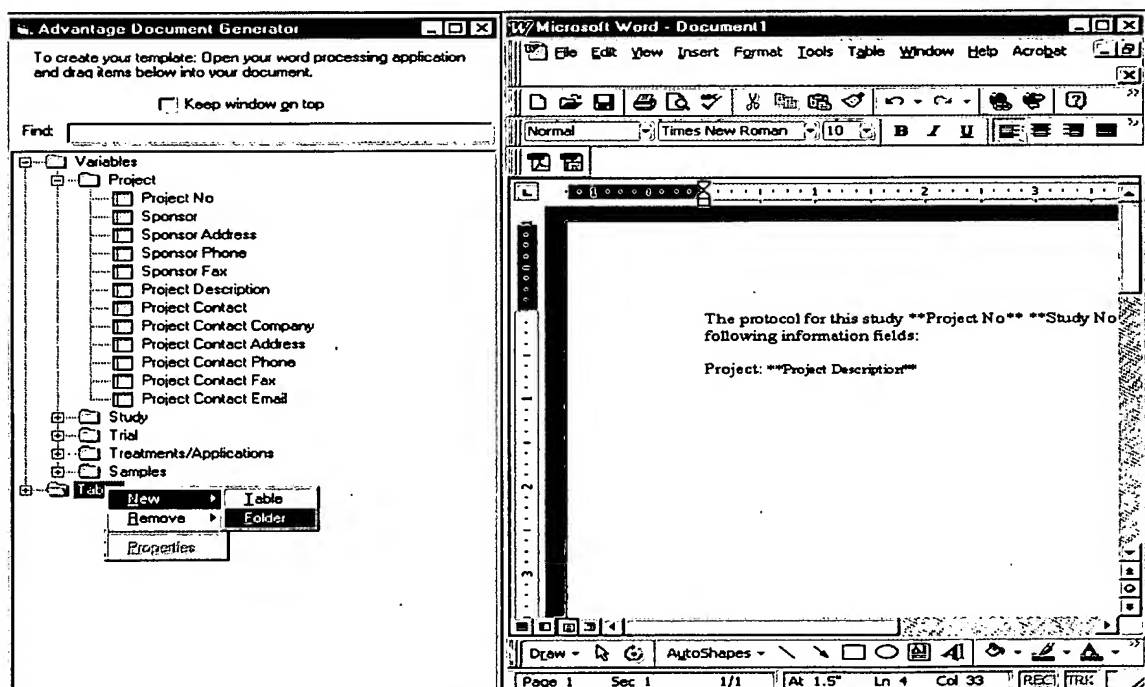
Variable & Tables Box – rtf Template

- When template construction is complete the user will need to click on Save or Save As in the Word Processor. When the box appears for saving the document the file type must be set as Rich Text Format (*.rtf). The user will then assign the template a File Name and save the document.

- The Rich Text Format (*.rtf) file type is what will be used with the iAdvantage software for the templates. Once completed the user must close the Word Processor and the Variables and Tables Box. Closing the Variables and Tables box will return them to the Document Generator Main Menu.

Variable & Tables Box – Tables Folder Function

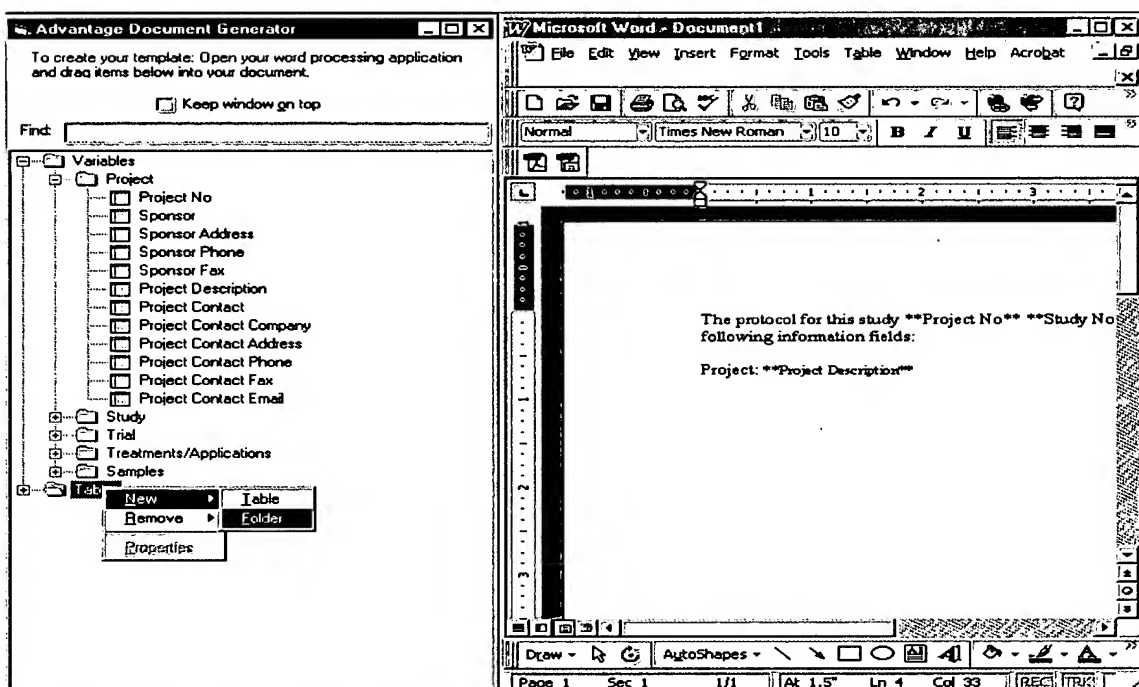
- Description – Allows user to create new tables, edit or delete existing tables, select tables to be placed into templates/documents and sort/group tables in folders & subfolders under the main Tables folder.



Tables are stored under the main Tables folder or in subfolders under this main folder. To view contents of folders click on the “+” symbol next to the folder or double click on the folder itself. To close the folder click on the “-” symbol beside the folder.

- 5 To add a new folder or table within a particular folder, click on that folder using the right mouse button. This will open a box with the options of “New”, “Remove” & “Properties”. Moving the cursor over either the “New” or “Remove” selection will open a second box with the choices of “Table” & “Folder”. “Properties” selection will always be grayed out when clicking on a Folder. This selection will only be available when
10 selecting a Table.

New – Allows user to create a new folder under the main Tables folder. Separate folders allows user to group tables for easier location.



- 15 **To add new folder:** Right click on folder under which new folder will be saved, Move cursor over “New” in box, select “Folder” from second box. The “New Folder” box below will then appear.

- 20 **New Folder Name** (input field, alphanumeric, unlimited) – User enters the name of the new folder to be created in this field.

OK – Creates a new folder in the specified location. After new folder created, Variable & Tables box will reappear with the new folder shown.

Cancel– Stops procedure and returns user to the Variables & Tables box screen.

5

Regardless of which folder under Tables was right clicked on, the new Folder created will always appear as a subfolder under the main Tables folder. It is not possible to create sub-subfolders.

10

Remove – Allows user to remove an existing Folder or Table from the system. If user right clicked on a Folder, then only the Folder option will be available for removal in the second box. If the user right clicked on a Table, then only the Table selection will be available in the second box..

15

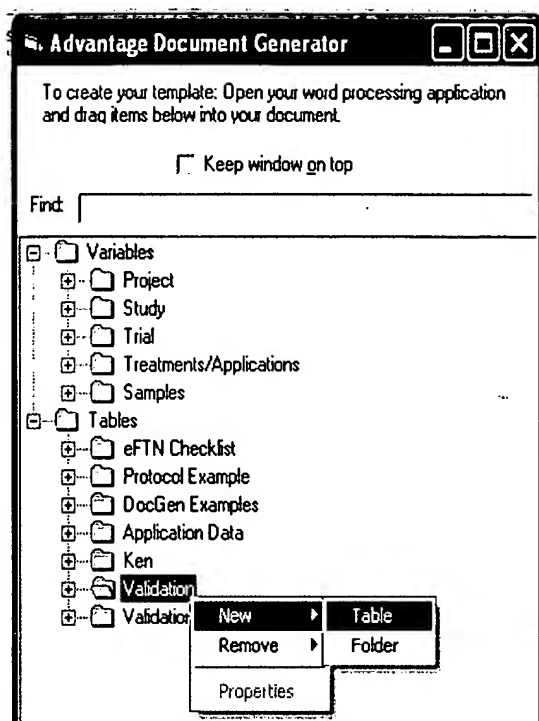
After user selects “**Remove**”, if no tables exist under this folder, a box will appear with the question: Are you sure you want to remove the folder “Name of Folder Selected”? If the user selects Yes , the selected folder will be removed and the Variables & Tables box will reappear with the folder removed. If the user selects No , the folder is not removed and the user is returned to the Variable & Tables box.

20

After user selects “**Remove**”, if tables exist under this folder, a box will appear with the statement: “You must first remove the tables in this folder to remove it.” There is only one choice; OK . Selecting “OK” returns user to the Variables & Tables box without removing the selected Folder. Folders containing Tables cannot be deleted/removed from the system.

25

Table Properties – If an existing Table was selected then properties will be available as a selection in the first box. Clicking on this option will open the Table Properties box that allows the user to edit the setup and contents of that Table.



5

- 10 User will right click on the folder where they want the new table to be located or where the table they wish to edit is located. A box with the choices "New", "Remove" and "Properties" (grayed out) will appear. If "New" is selected a second box containing the choices "Table" and "Folder" will appear. The explanation for the "Remove" was described previously.

Table Properties

Table

Folder:

Name:

Columns

Available

Find:

Project

- Project No
- Sponsor
- Sponsor Address
- Sponsor Phone
- Sponsor Fax
- Project Description
- Project Contact
- Project Contact Company
- Project Contact Address
- Project Contact Phone
- Project Contact Fax
- Project Contact Email

Study

- General Study
- Formulations
- Active Ingredients

Used in this table

Project No

Sponsor

Sponsor Address

Up

Down

Query Conditions

Table Format

☐ Create as Text String

OK

- 5 **Folder** (drop-down list) – The name of the folder selected to create the table under will appear in this field when the box appears. The drop-down list also contains the name of all the folders under the main Table folder.

{Table} Name (required input field, alphanumeric, unlimited) – User enters the name for the new table in this field.

- 10 **Find** (field) - The user can type in the name of a variable they wish to find into this field and it will be shown in the Variables or Tables tree in the box below this field. As the user types, the program will search for variable names that match what is being typed in the Find field as it is being typed. The first variable matching what has been typed so far will be displayed in the tree. That variable may then be selected from the tree, by
- 15 clicking on it.

- Variables Box** – The folders in this box may be clicked on to reveal the subfolders or variables beneath it. The “+” or “-” symbols beside each folder also allow opening and closing of the folders in the tree. The “+” symbol may be clicked on to reveal the subfolders or variables beneath it and the “-” symbol clicked on to close the tree to only show the folder name beside it.

Adding variables to and deleting variables from the table box.

- To move the variables from the variables box on the left to the “Used in the table” (table) box on the right** the user may select a variable from the list and then drag and drop the desired variable to the table box. The user may also select the desired variable in the variables box and then use the right pointing double arrows located between the boxes to move the variable to the table box.
- To delete/remove a variable from the list in the table box**, the user will first click on the desired variable and then click on the left pointing double arrows button between the boxes. The variable will no longer appear in the table box.
- Up & Down** – These buttons located to the right of the tables box can be used to move a variable up or down in the list of variables placed in the table box. This allows the user to reorder/re-sequence the list of variables as they will occur in the table.
- Query Conditions**– Allows the user to limit or restrict the data to be included for one or all the variables in the table. When user selects this function a “Query Conditions” box will appear on the screen.

Column	Condition	Parameter

Top Left Drop-down List - The variables that were put into the table box will be found in the drop-down list at the top left of the Query Conditions box.

5 **Center Drop-down List** – Allows the user to set the general conditions to be used with the specific parameters for the query for the selected variable. Choices in the drop-down list are “equal to”, “not equal to”, “greater than” and “less than”.

10 **Equal to** – User can specify a specific parameter so that only that only data that meet that parameter within that variable will be pulled from the database during the query.

Not Equal to – Allows the user to specify a specific parameter that will not be pulled for that variable during the query.

15 **Greater than** – Allows the user to set a parameter that will restrict the data pulled during the query to only that data that is greater than the parameter stated.

20 **Less than** - Allows the user to set a parameter that will restrict the data pulled during the query to only that data that is less than the parameter stated.

Top Right Input Field – This is the field where the detail portion of the query parameter is entered by the user. This field is used in conjunction with the parameter delineators in the center drop-down list.

25 **Add** – Once the three boxes at the top of the box have been filled in, setting the query parameters for that variable, the “Add” button allows the user to save this query for this table. After selecting “Add” the variable and the query parameters will appear in the query display box. This box contains the column headers “Column”, “Condition” and “Parameter”.

30 **Update** – Allows the user to edit an existing query in the query display box. User will click on the particular query in the display box to be edited and it will be displayed in the boxes at the top. After the user changes the desired field(s) they will click on “Update” and the query will be saved back to the list with the changes included.

35 **Remove** – Allows the user to remove an existing query from the query display box. User will click on the particular query in the display box to be removed and then click on “Remove”. The selected query will then be removed from the list in the query display box.

40 **OK**– When the user has finished creating, editing and/or removing queries for the selected variables for this table they will click on the “OK” button to close the Query Conditions box.

Table Properties

Table

Folder: Validation

Name: TestFS

Columns

Available

Find:

- ☐ Project
 - ☐ Project No
 - ☐ Sponsor
 - ☐ Sponsor Address
 - ☐ Sponsor Phone
 - ☐ Sponsor Fax
 - ☐ Project Description
 - ☐ Project Contact
 - ☐ Project Contact Company
 - ☐ Project Contact Address
 - ☐ Project Contact Phone
 - ☐ Project Contact Fax
 - ☐ Project Contact Email
- ☐ Study
 - ☐ General Study
 - ☐ Formulations
 - ☐ Active Ingredients

>>

<<

Used in this table

- Project No
- Sponsor
- Sponsor Address

Up

Down

Query Conditions

Table Format

☐ Create as Text String

OK

Variable & Tables Box – Table Format

- 5 Allows user to adjust the column widths for the table being created or edited.

Click on **Table Format**

Table Format Properties																			
Adjust this table's column widths as they appear below																			
Inches :	1	:	2	:	3	:	4	:	5	:	6	:	7	:	8				
cm	2		4		6		8		10		12		14		16		18		20
Project No	Sponsor	Sponsor ...																	
OK																			

- 5 User may place their cursor on the vertical lines between the variables shown in the box. The user can then click on the vertical line and while holding down the left mouse button move the cursor until the desired width for that variable's column is achieved. Letting go of the left mouse button at that point will then set the column to that width. This may be done for each variable in the table

- 10 **Measurements** in "inches" and "cm" will be shown in the box above the variable to allow the user to see how with each variable and the entire table is.

OK – Once the user has set the column widths they will click on the "OK" button to close the Table Format Properties box

15

Table Properties

Table

Folder:

Name:

Columns

Available

Find:

- [-] Project
 - [+] Project No
 - [+] Sponsor
 - [+] Sponsor Address
 - [+] Sponsor Phone
 - [+] Sponsor Fax
 - [+] Project Description
 - [+] Project Contact
 - [+] Project Contact Company
 - [+] Project Contact Address
 - [+] Project Contact Phone
 - [+] Project Contact Fax
 - [+] Project Contact Email
- [-] Study
 - [+] General Study
 - [+] Formulations
 - [+] Active Ingredients

>> <<

Used in this table

- Project No
- Sponsor
- Sponsor Address

Up Down

Query Conditions Table Format

☐ Create as Text String

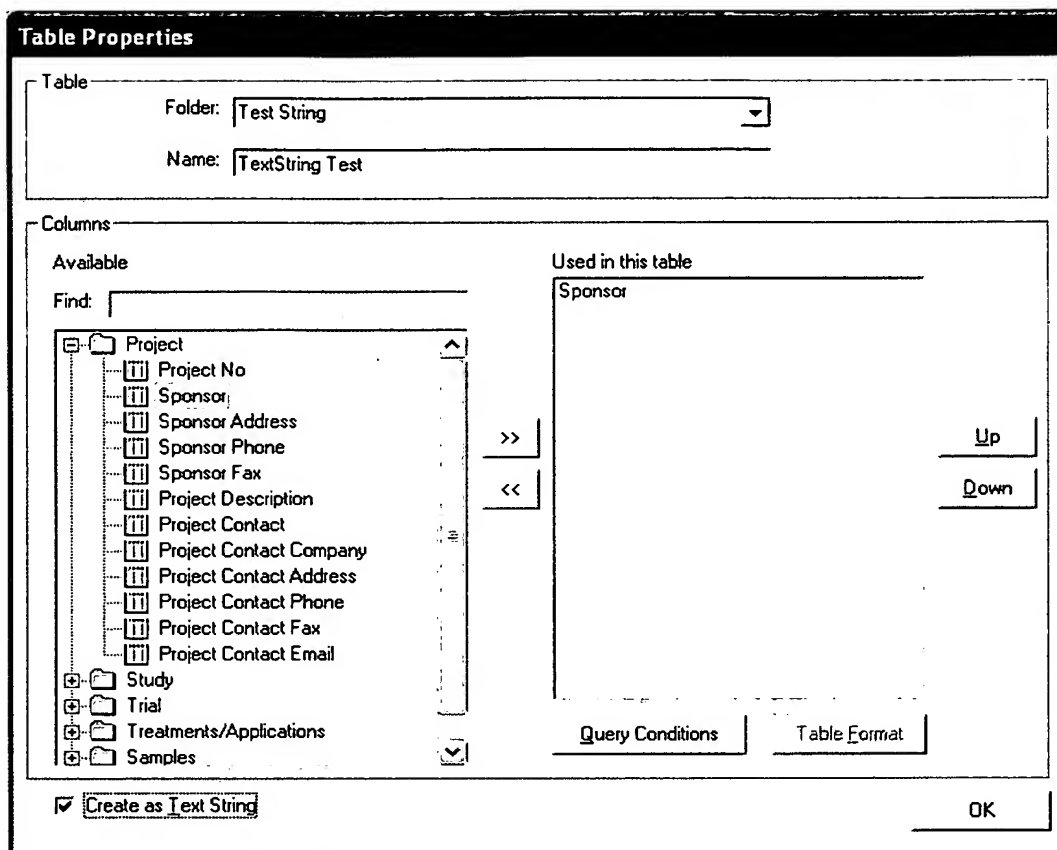
OK

- 5 **OK** – Once the user has completed creating or editing the particular table, clicking on “OK” will save the table and close the Table Properties box. If a new table was created the table will now appear under the folder where it was created in the list of tables in the Variables & Tables box.

Variables & Tables Box – Text Strings

A text string is a comma-delimited list of records for a variable. This allows the user to create a text string, using variables from the variable list that can be inserted into text sections of the document templates.

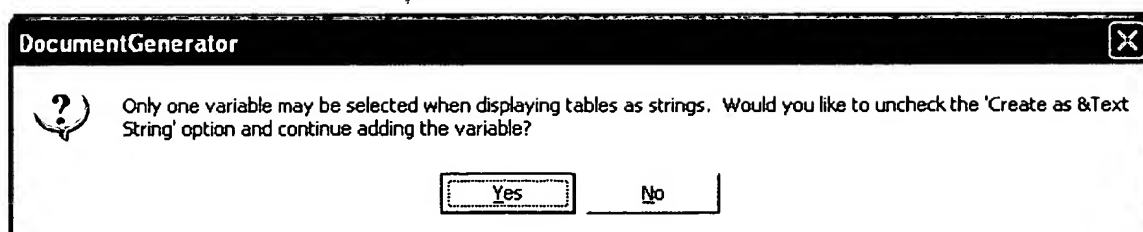
5



- 10 **User selects a single variable from the Variables box (display box on left side of Table Properties box) and place it into the Table box. After the variable has been selected the user may click on the Create as Text String box.**

If user tries to place more than one variable in the Table box the following box will appear.

15



If user selects “Yes” they will be returned to the Table Properties box and the “Create as a Text String” box will now be unchecked. The second variable they were attempting to add to the Table box will now be added to that box.

- 5 If user selects “No” they will be returned to the Table Properties box, the “Create as a Text String” box will still be checked and only the first variable selected will appear in the Table box.
- 10 **Create as a Text String** (checkbox) – Clicking on the checkbox next to “Create as a Text String” places a check in the box. Box is always unchecked when Table Properties box is opened. Checking the box allows the user to specify a variable from the variables list to be set up as a text string to be inserted into document templates.
- 15 **Table Format** - Once the box is checked the “Table Format” button is dimmed and is no longer accessible.

Query Conditions - This button is still available and conditions can be set for text strings as previously described.

- 20 **OK** - Once the user has completed creating or editing the particular text string, clicking on “OK” will save the text string and close the Table Properties box. If a new text string was created it will now appear under the folder where it was created in the list of tables in the Variables & Tables box.

25

To edit a previously saved Text String the user will select the file from the Table list and the Table Properties box will open. The user may then set/change query conditions or may change the variable selected for this text string. Once the changes have been made the user will click on the OK button to save the changes and exit the Table Properties box.

30

To change a previously selected variable in a text string the user must first delete/remove the variable in the Table box and then may add the new variable to the Table box. If the user does not delete the previously saved variable first they will get the message shown above for multiple variable is a text string.

35

8.4 Document Generator - Copy/Upload Template/Table to iAdvantage

Allows the user to upload templates and tables to iAdvantage database. Templates and Tables must be uploaded to the database in order to be available for document generation.

- 5 Clicking on the “Copy/Upload Template/Table” link on the Document Generator Main Menu screen will bring the user to the following screen (Copy/Upload Files to iAdvantage).

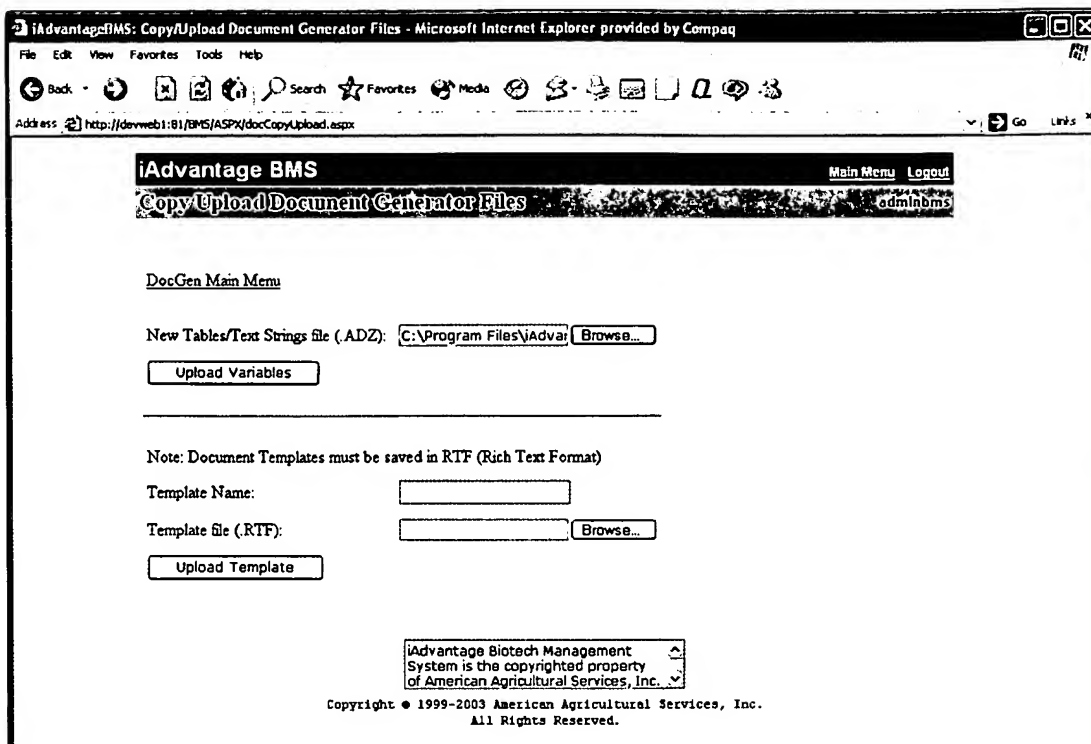
10

DocGen Main Menu – Allows the user to return to the Document Generator Main Menu without performing any functions on this screen.

- 15 **New Tables/Text Strings File (.ADZ):** (field) – User can either type in the location and name of the file containing the Tables and Text Strings to be uploaded to iAdvantage or can use the “Browse” button , next to this field, to locate and select the file. Location for this file will be on the hard drive of the user’s computer under the directories “Program Files/iAdvantage Document Generator/”. The file name will be “Variables.adz”. The selected filename and location will now appear in this field.

20

After selecting the file using the browser the Copy/Upload Files to iAdvantage screen will return with the file shown in the New Tables/Text Strings field.



Upload Variables – Clicking on the button uploads the selected Table or Text String “.adz” File to the iAdvantage database on the webserver site.

5

While uploading the file a note will appear on the screen indicating “Importing variables ... Please Wait.”.

When finished, the message “Variables were imported successfully. Click here to return to Document Generator.” will appear on the screen. Clicking on “here” in this statement will then return the user to the Document Generator Main Menu.

10

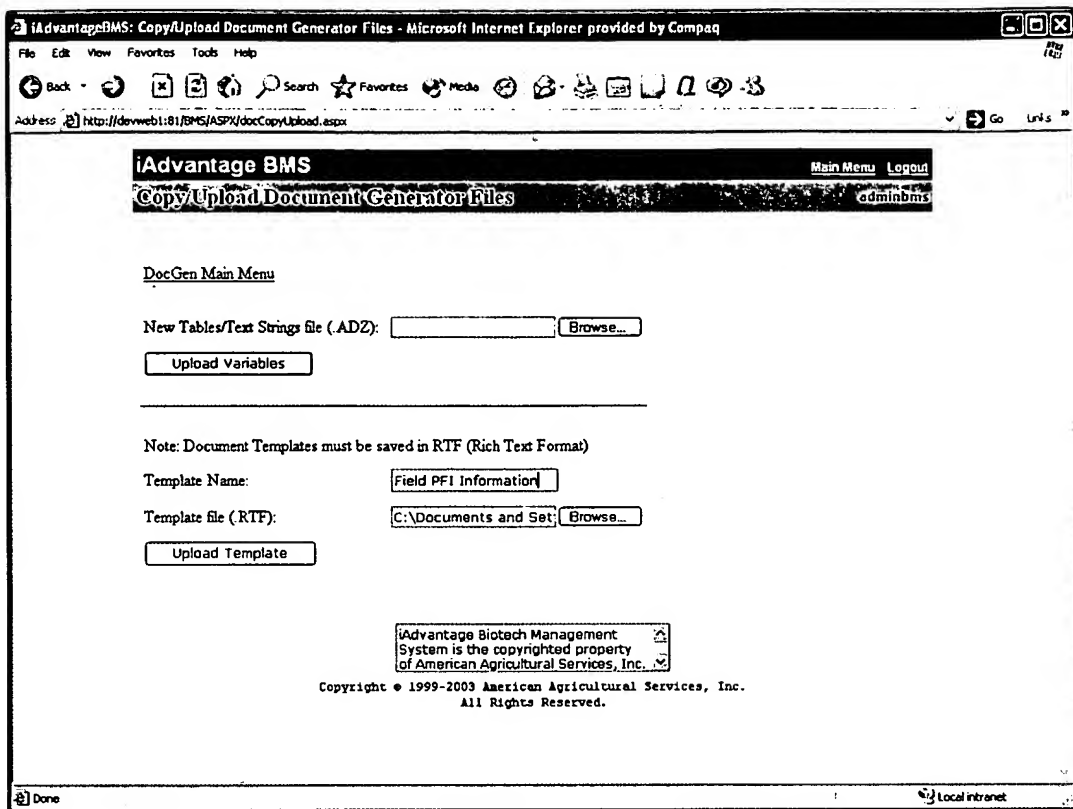
Template Name (required, up to 50 alphanumeric characters) Allows user to enter a descriptive name for the template. This is the name that will be displayed in the Templates display box in the Document Generation section.

15

Template file (.RTF) - User can either type in the name of the Template to be uploaded to iAdvantage or can use the “Browse” button , next to this field, to locate and select the file. Location for this file will be on the hard drive of the user’s computer. The file will be in Rich Text Format (.rtf). The user will locate and select the template file to be uploaded to iAdvantage. Once selected, from the browser the filename and location will now appear in the “Template file (.RTF)” field.

20

25



After selecting the file using the browser, the Copy/Upload Files to iAdvantage screen will return with the file shown in the Template field as shown below.

5

Upload Template – Clicking on this button uploads the selected Template (.rtf file type) to the iAdvantage database on the webserver site.

10 While uploading the file a note will appear on the screen indicating “Storing your template ... Please Wait.”

When finished, the message “Operation was Successful” will appear near the top of the screen.

15 When finished, the message “Your template was uploaded successfully. Click here to return to the menu.” will appear. Clicking on “here” in this statement will then return the user to the Document Generator Main Menu.

20 In the upper right-hand corner is the Log-out link and the Main Menu link.

8.5 Document Generator – Document Generation – Templates/Documents

Allows the user to download templates for review/edit and to create documents using the variable data collected and document templates.

5

DocGen Main Menu – Allows the user to return to the Document Generator Main Menu without performing any functions on this screen.

10

Project (drop-down list) – Clicking on this box will display a drop-down list with all project codes that the user is authorized to access. User may select a single project code from the list or may select “Use All Projects” in which case all projects will be queried to obtain the data requested in the template(s). Either all Projects may be chosen for document generation or a single project may be chosen. Combinations of various Projects are not allowed.

15

If “Use all projects” is chosen from the Projects drop-down list then Study Plan and Site fields will remain unchanged on the screen. Also the dropdown display boxes in these fields remain empty. Neither individual Study Plans nor Sites can be selected when “Use all Projects” is selected.

20

5 **If a single project is chosen** from the Projects drop-down list then a checkbox labeled “Use Multiple Study Plans” will appear under the Study Plan field. “Use All Study Plans...” will now appear as the default in the Study Plan field drop-down list and “Use All Sites...” will appear as the default in the Site field drop-down list. Clicking on the Study Plan drop-down list will reveal all Study Plans available for the Project selected. At this point the only choice in the Sites field is “Use All Sites...”.

10 **Study Plan (drop-down list)** – Clicking on the box will display a drop-down list with all available studies for the project selected shown. What is shown in the Study Plan field/box will be dependent on what is selected in the Project drop-down list.

15 **If “Use All Study Plans...” is selected** from the drop-down list, all Study Plans for the selected Project will be used to create the document. “Use all Sites...” will be the only choice available in the Sites drop-down list. Individual sites cannot be selected when all Study Plans are being queried for document creation/generation.

20 **If a single Study Plan** is selected from the drop-down list the screen will refresh and the selected Study Plan will appear in the Study Plan field display. “Use All Sites...” will still appear in the display field for Sites but the user can click on the drop-down list and all the Sites assigned to that Study Plan will appear in the drop down display field for Sites.

25 **Use Multiple Study Plans (check box)** – Allows the user to display all the study plans listed for that project at once. Displaying all the study plans at once will allow the user to pick multiple study plans to pull information from rather than just one or all. Checking the box displays all the study plans. The default for the box is unchecked.

30 The user may then select as many studies from the list as they choose. Selection of multiple studies from the list will be done by selecting one Study Plan and then holding down either the Control key or Shift key to select other files or groups of files just as is done in Windows for selecting files. “Use all Sites...” will be displayed in the Sites drop-down list display. If the user clicks on the drop down display box for Sites then all the Sites for each Study Plan selected in the Study Plan display box will be displayed. The user may either choose “Use All Sites...” or they may choose a single Site form the list.

35

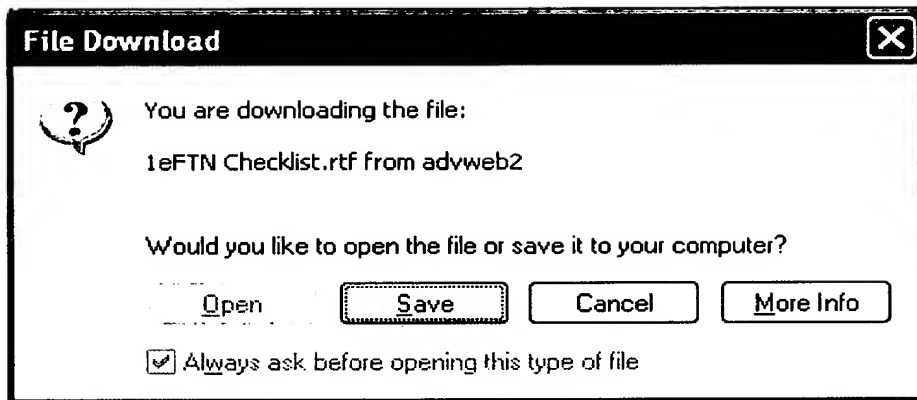
40 **Site (drop-down list)** – Clicking on the box will display a drop-down list with all available Sites for the Project and Study Plan combination selected. What is shown in the Site field/box will be dependent on what is selected in the Project and Study Plan drop down lists.

45 **Template (scrollable display box)** – Lists the templates available to be downloaded from the iAdvantage system or to be used in Document Generation. Templates are selected by clicking on them. Only one Template can be selected at a time.

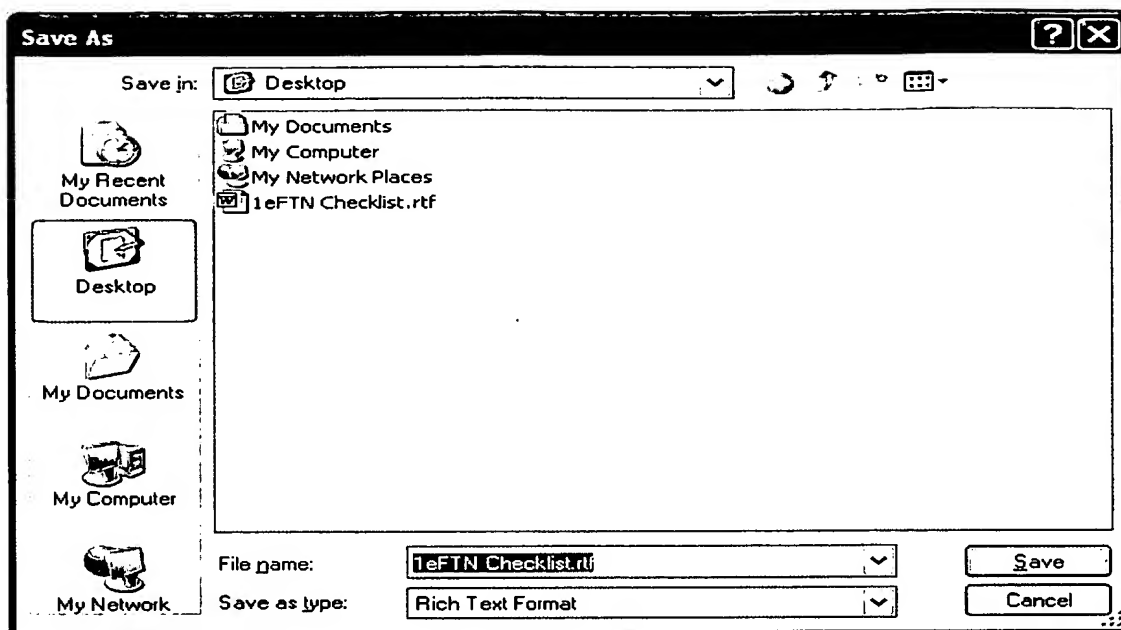
Download Template – Allows user to download the selected template from the Template display box to the user's computer.

5 To download a template from the iAdvantage system the user will click on
 "Download Template" on the Document Generation screen. Prior to clicking on
 the Download Template button the user must select a template to download from
 the Template display box by clicking on it. If the user does not first select a
 template the user will see a screen on their browser indicating that they are not
 10 authorized to view this page. The user may then use the browser back button to
 return to the Document Generation screen.

After the user has selected a template to download and clicks on Download
 Template button a download box will appear. The user will choose to Save the
 15 template to their computer. Example screens of the download procedure follow.

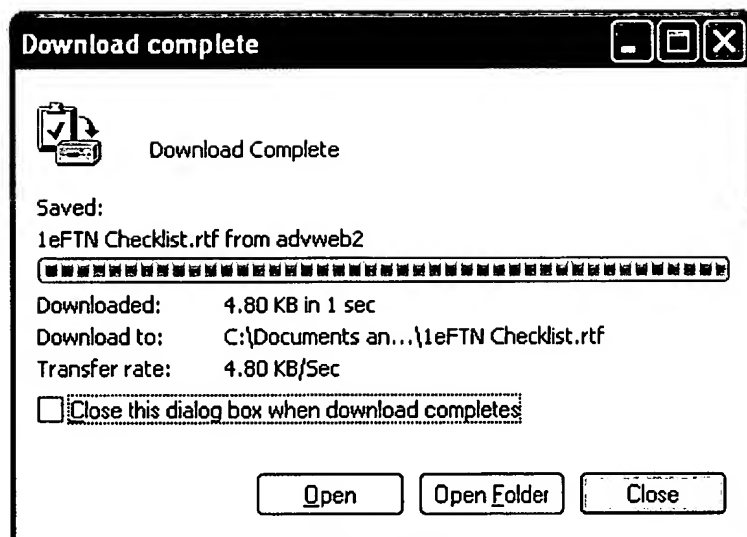


20 Next a Save As box will appear on the screen with the name of the selected
 template file entered in the File field. The file format of the file must be .rtf (rich
 text format). The user will need to select the location on their computer to save
 the template to and Save the file. If the file already exists in that location the user
 will be asked if it is OK to overwrite the existing file.



The following is an example of a box that will appear letting the user know that the download process is complete. The user will then choose to close this box.

5



The selected template has now been downloaded to the designated location on the user's computer.

10

To edit the downloaded template the user would open the template file using any word processing software. Edits/revisions may then be made directly to the template document. To add tables and/or text strings to the document the user would minimize or reduce the size of the word processor screen and go to the Table Properties screen of the Template/Table Generation option in the Document Generator Main Menu. Editing and Uploading the revised template were discussed earlier.

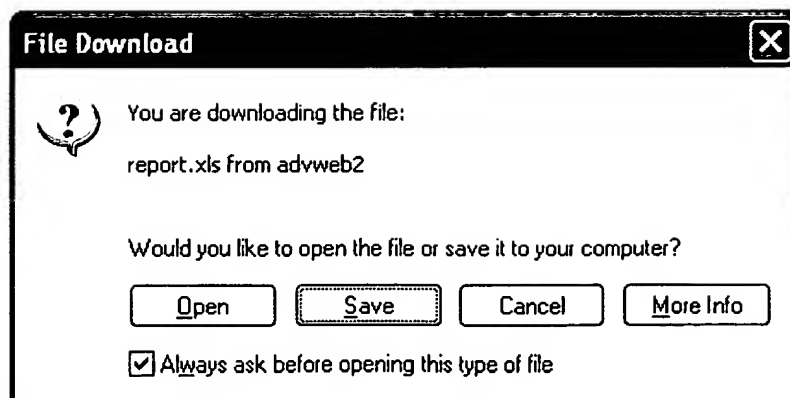
Generate Spreadsheet – Allows user to create an Excel spreadsheet using the template selected and Project/Study Plan(s)/Site(s) selected. Generate Spreadsheet is used only with tables created in Document Generator and not text strings.

The user must select the combinations of Project, Study Plan(s) and Site(s) that they wish to pull data from and choose a template to use before choosing this option.

If the user does not choose a Project, Study Plan(s) and/or Site(s) then the system will pull the data for the selected template into the spreadsheet from all Projects which will include all of the Study Plans and Sites under all of the Projects in the system. This will be done because “Use all Projects...” is the default in the Project selection field on this screen.

If the user does not choose a template an error message will appear on the screen stating “You need to select a Template”. “OK” is the only selection for exiting this box. Upon selecting OK the user is returned to the Document Generation screen.

After the user has selected the combination of Project(s), Study Plan(s) and Site(s) they want to pull the data from and has selected a template to use they may click on Generate Spreadsheet. When this is selected the system will query the iAdvantage database for the selected parameters and template and, produce an Excel spreadsheet. The following screen is an example of a screen that the user will see once the system has compiled the data into a spreadsheet.



The first screen the user will see once the system has pulled all the required data is a download screen. The user may Open the Excel spreadsheet in their browser or may Save the spreadsheet to their computer.

5 If they choose to **Save the Excel spreadsheet** they will see a Save As box to allow the user to save the spreadsheet to the desired location on their computer. After completing the Save procedure the user will be returned to the Document Generation screen. The user may then open the file using Excel to work on it and/or print it on their computer.

10 If they choose to **Open the Excel spreadsheet** the spreadsheet, the spreadsheet will appear in their browser screen for viewing and editing. The file can then be printed or saved from the browser screen if desired. The user can use the back button on the browser to return to the Document Generation screen.

15 **Generate Document** – Allows user to generate a document using the template and Project/Study Plan(s)/Site(s) selected on this screen. Document will be generated and then can be viewed or saved to user's computer. See Section 8.18 for details of document generation process.

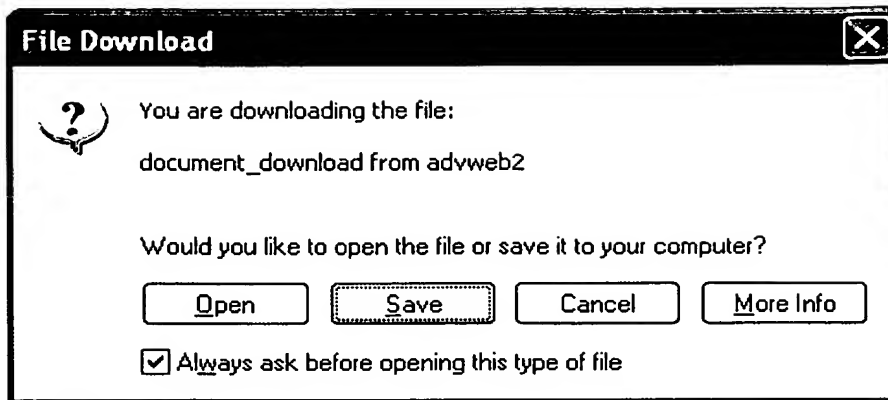
20 **The user must select the combinations of Project, Study Plan(s) and Site(s) that they wish to pull data from and choose a template to use before choosing this option.**

25 If the user does not choose a Project, Study Plan(s) and/or Site(s) then the system will pull the data for the selected template into the document from all Projects which will include all of the Study Plans and Sites under all of the Projects in the system. This will be done because "Use all Projects..." is the default in the Project selection field on this screen.

30 If the user does not choose a template an error message will appear on the screen stating "You need to select a Template". "OK" is the only selection for exiting this box. Upon selecting OK the user is returned to the Document Generation screen.

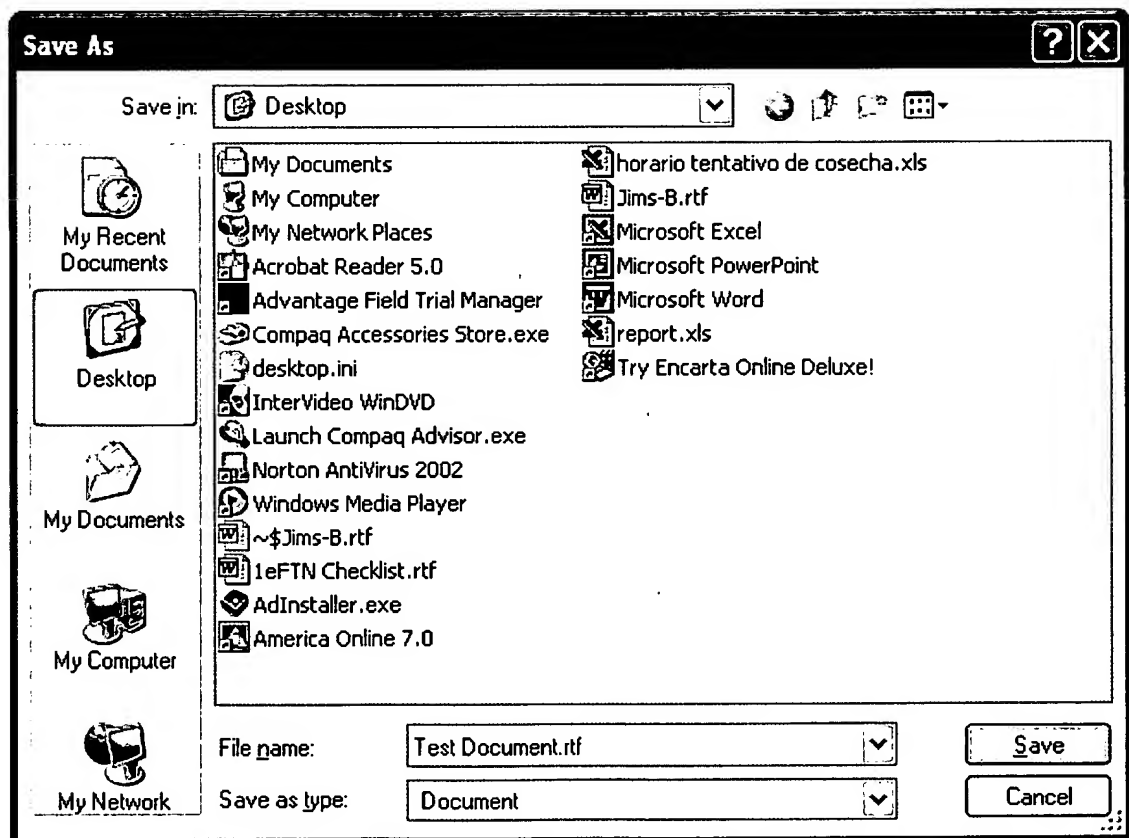
35 After the user has selected the combination of Project(s), Study Plan(s) and Site(s) they want to pull the data from and has selected a template to use they may click on Generate Document. When this is selected the system will query the iAdvantage database for the selected parameters and template and, produce a document. The following screen is an example of a screen that the user will see once the system has compiled the data into a document.

40



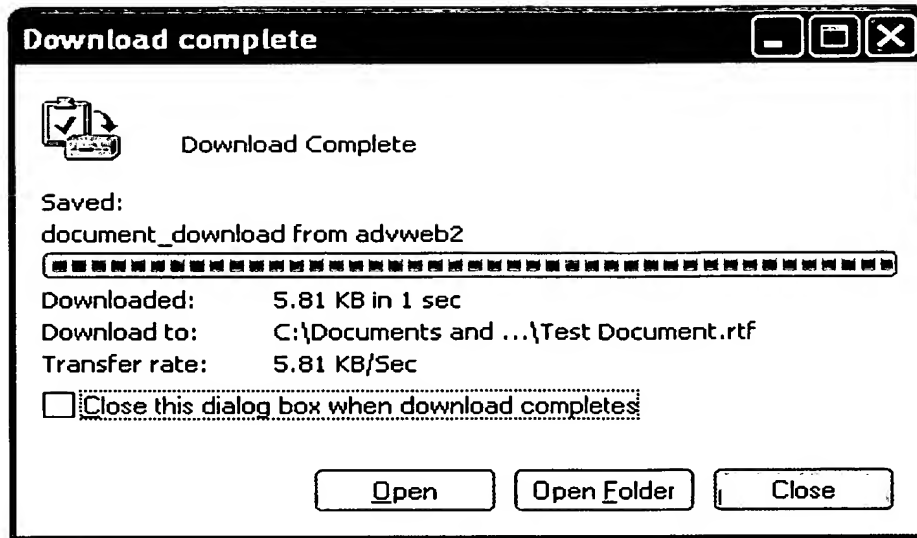
5

The option the user should choose here is Save. Upon choosing Save a Save As screen will appear (see below). The user will then need to rename the document with the appropriate file extension for the word processing software they will be using to view the document.



10

After the file has been saved a screen similar to the one below should appear. The user will close the box. After closing the box the user will be returned to the Document Generation screen.



The file is now located on the user's computer and it can be opened and then viewed/edited in the user's word processing software.

5

Delete Template – Allows the user to delete a template from the list of Templates. User will click on the template to be deleted and then click on Delete Document. The user will then be asked: “Are you sure you want to delete?”. Two answer options are OK & Cancel. If Cancel is chosen then the user will be returned to the Document Generation screen and the template will not be deleted. If OK is chosen a warning box will appear stating “*****Warning***** once deleted this template will no longer be available for use in document generator.” Warning box will include OK and Cancel button. Cancel returns user to Document Generation screen. If OK is chosen the screen will be refreshed, the selected template will no longer be available in the list and the user will be returned to the Document Generation screen.

10

15

In the upper right-hand corner is the Log-out link and the Main Menu link.